

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

DAIICHI PHARMACEUTICAL CO., LTD. and  
DAIICHI PHARMACEUTICAL CORPORATION,

Plaintiffs,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants.

Civ. No. 03-937 (WGB)

MEMORANDUM OPINION

APPEARANCES:

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**BASSLER, SENIOR DISTRICT JUDGE:**

Defendants Apotex, Inc. and Apotex Corp. (collectively as "Apotex" or "Defendants") filed two motions *in limine*: (1) to exclude the expert report and testimony of Richard Killworth; and (2) to exclude the expert report and testimony of Dr. Phillip Beutel.

Plaintiffs Daiichi Pharmaceutical Co. Ltd., and Daiichi Pharmaceutical Corporation (collectively as "Daiichi" or "Plaintiffs") filed a motion *in limine* to exclude or limit the expert testimony of Joseph Robinson.

For the reasons set forth below, Defendants' motion is **denied**, and Plaintiffs' motion is **denied**.

**I. DISCUSSION**

Rule 702 of the Federal Rules of Evidence, which governs expert testimony, provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Under the Federal Rules of Evidence, the judge has a gatekeeping responsibility to "ensure that any and all scientific

testimony or evidence admitted is not only relevant but reliable." Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589 (1993). The purpose of the gatekeeper function "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 152 (1999). In Elcock v. Kmart Corp., 233 F.3d 734 (3d Cir. 2000), the Third Circuit held that "before an expert witness may offer an opinion pursuant to Rule 702, he must first be qualified by virtue of specialized expertise." 233 F.3d at 741. While the Circuit employs a liberal standard of qualifying experts, an expert's testimony may, nonetheless, be excluded if his specialized experience is in a field or specialty that is not directly on point with the matter before the court. Elcock, 233 F.3d at 742; see also Aloe Coal Co. v. Clark Equip. Corp., 816 F.2d 110 (3d Cir. 1987). An expert's conclusion may be drawn from a set of observations based on extensive and specialized experience, but his opinion must be more than mere speculation. See Daubert, 509 U.S. at 590; Elcock, 233 F.3d 745. If it is determined that the expert's opinion has a reliable basis in the knowledge and experience of his discipline and is relevant to the matter before the court, the expert is permitted wide latitude to offer opinions,

including those that are not based on firsthand knowledge or observation. Daubert, 509 U.S. at 592; Kumho Tire, 526 U.S. at 148.

A. Richard Killworth

Apotex requests that the Court exclude the expert testimony of Richard Killworth, arguing that he does not qualify as an expert witness under Fed. R. Evid. 702. Defendants contend that Mr. Killworth has limited experience at the U.S. Patent and Trademark Office ("PTO") and that he is unfamiliar with the regulations enacted since his three years' employment at the PTO from 1967 through 1970. Additionally, Apotex argues that Mr. Killworth has no "specialized knowledge" because he was not employed at the PTO at the time of the prosecution of Daiichi's U.S. Patent No. 5,401,741 ("the '741 patent").

Apotex's arguments are not credible. It is not necessary that Mr. Killworth have worked at the PTO during a specific time frame to opine on PTO practice and procedure. The Court finds no support for this contention. The plain language of Rule 702 clearly provides that work experience at a certain period in time is not a determining factor in qualifying a witness as an expert. Rule 702 requires that an expert witness have specialized knowledge, the basis of which "can be practical experience as well as academic training and credentials." Elcock v. Kmart Corp., 233 F.3d 734, 741 (3d Cir. 2000). Mr. Killworth qualifies

as an expert because of his experience with the PTO in combination with the specialized skills and knowledge he has gained from his extensive work experience in the field of patent law.

Mr. Killworth has over 35 years' experience in patent law as a patent examiner, law clerk and technical advisor to Judge Almond of the United States Court of Customs and Patent Appeals, and as a registered patent attorney. Kidd Decl., Exhibit A. In addition, he has taught patent law and procedure at numerous law schools and as a CLE instructor, and he has extensively published articles on patent law. Id.; Daiichi Opp. Br., p.2. In his teaching capacity, he has lectured on the requirements for satisfying the duty of candor during the prosecution of patents. Killworth Deposition on Dec. 8, 2004, at 29:22-25. Clearly, Mr. Killworth has specialized knowledge and has kept informed of new requirements and changes in patent law, which, in addition to his work experience with the PTO, qualifies him as an expert on the practice and procedures of the PTO.

"Under Rule 702, an expert can be employed if his testimony will be helpful to the trier of fact in understanding evidence that is simply difficult, though not beyond ordinary understanding." United States v. Downing, 753 F.2d 1224, 1229 (3d Cir. 1985) (internal citations omitted). The trial judge has broad discretion in admitting expert evidence. See Salem v.

United States Lines Co., 370 U.S. 31, 35 (1962). The Court will allow Mr. Killworth's testimony because it is relevant and it will be beneficial to the Court's understanding of the technical requirements of patent prosecution.

B. Doctor Phillip Beutel

Apotex also seeks to exclude the expert testimony of Doctor Phillip Beutel since he does not qualify as an expert under Fed. R. Evid. 702 on the subject of the commercial success of Daiichi's patented product, FLOXIN® Otic ("Floxin").<sup>1</sup> Apotex contends that Dr. Beutel should be barred from testifying because his report and opinion are primarily based on information provided to him by Daiichi "with virtually no independent or *objective* investigation or verification of the information provided." Apotex Br., p. 6 (emphasis in original). Apotex argues Dr. Beutel's opinions and testimony are not the product of reliable principles and methods and, furthermore, he lacks the experience necessary to form his conclusions.

Dr. Beutel is an economist and Vice President at National Economic Research Associates, an economic consulting firm that evaluates the market for patented inventions, calculations of economic damages, and the valuation of intellectual property.

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<sup>1</sup>The Court will not address Daiichi's contention that Apotex failed to specifically identify Dr. Beutel's testimony and report as a planned motion *in limine* in the final pretrial order in violation of Fed. R. Civ. P. 16(e) because the issue is now moot since the Court denies Apotex's motion.

Livaccari Decl., Exbt. B at 2. Dr. Beutel has also taught undergraduate and graduate level economics at Miami University in Oxford, Ohio. Id.

Apotex's arguments that Dr. Beutel's opinions are not reliable because he has never been employed by a pharmaceutical company and has limited experience in evaluating the issue of commercial success are unavailing. An expert may be qualified to testify even though the court, or the opposing party, feel he is not the 'best' qualified. Holbrook v. Lykes Bros. Steamship Co., Inc., 80 F.3d 777, 782 (3d. Cir. 1996).

Whether Dr. Beutel's opinions are reliable depends upon whether they are based in a valid scientific method or, alternatively, his experience and knowledge. Consideration of a product's commercial success is an acceptable method of determining whether an invention was obvious at the time of its patent. The Supreme Court held in Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966), that commercial success "might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, [this inquiry] may have relevancy."

Significant sales in a relevant market often demonstrate the presence of a commercially successful product and help rebut a challenge of obviousness. J.T. Eaton & Co. v. Atlantic Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997); Ecolochem, Inc.

v. Southern Cal. Edison Co., 227 F.3d 1361, 1377 (Fed. Cir. 2000). Plaintiffs argue that Dr. Beutel used reliable market data and other information to reach his conclusion that Floxin has been commercially successful. Daiichi supports their claims by citing several cases for approving as statistically sound the data used by Dr. Beutel in his conclusions. See e.g., Purdue Pharma L.P. v. Endo Pharms. Inc., 70 U.S.P.Q.2d 1185, 1199 (S.D.N.Y. 2004); In re Brand Name Prescription Drugs Antitrust Litigation, No. 94-cv-897, 1999 WL 639173, \*3 (N.D.Ill. Aug. 17, 1999). Defendants, on the other hand, provide nothing more than conclusory allegations and out of context deposition statements in support of their claims that Dr. Beutel's analysis is not scientifically sound. The Court notes that Apotex's argument that Dr. Beutel only used information provided by Daiichi is disingenuous because his report clearly states that he and his staff considered Apotex's own experts' reports. Livaccari Decl., Exbt. B at 2. Additionally, as noted by Plaintiffs, Dr. Beutel relied on market data generally accepted in the pharmaceutical industry and, in fact, by Apotex. Daiichi Opp. Br. at 7. Dr. Beutel testified that he also took steps to independently corroborate the data he used. 12-10-04 Deposition of Dr. Beutel, at 24: 5-16.

The Court is satisfied that Dr. Beutel has extensive experience in economics, used reliable methods in formulating his



conclusions, and is qualified to opine on the issue of Floxin's commercial success.

C. Professor Joseph Robinson

Daiichi seeks to exclude or limit the scope of Apotex's expert, Professor Joseph Robinson, on the ground that he does not qualify as a person of ordinary skill in the art or as an expert in the method of treatment claimed in the '741 patent.

The Court conducted a *Markman* proceeding on the claims contained in the '741 patent and in its Opinion made the determination that a person of ordinary skill in the art is a general practitioner or pediatrician. Daiichi now bases its argument to exclude Professor Robinson on the Court's construct of the ordinary person skilled in the art.

Daiichi argues that Professor Robinson's proposed testimony regarding prior art falls outside his area of expertise because he is not a general practitioner or pediatrician with experience treating ear infections.

The Court is not persuaded by these arguments. The purpose of defining the person of ordinary skill in art is not to set a ceiling as to who qualifies as an expert. The ordinary person skilled in the art is an objective test used to determine how disputed terms in the claim language of a patent should be defined. Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed. Cir. 1995). Elaborating further, the Federal Circuit held

in Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd., 122 F.3d 1040, 1042 (Fed. Cir. 1997), that "[t]he 'person of ordinary skill in the art' is a theoretical construct used in determining obviousness.... To suggest that the construct applies to particular individuals could mean that a person of *exceptional* skill in the art would be disqualified from testifying as an expert because not ordinary enough." (Emphasis in original). The fact that Professor Robinson does not fit within the standard of the ordinary person skilled in the art as defined in the Court's prior Opinion on claim construction, does not render him unqualified to testify on the issue of prior art. To the contrary, he is exceptionally qualified to opine on the issue of prior art of otic products. Professor Robinson has an extensive background in the design and development of products used to treat ear infections as well as more than 40 years' experience teaching pharmacy and medical students about drug delivery systems and preparation of otic solutions. Livaccari Decl., Exbt. A.

Professor Robinson's testimony will be useful to the Court's understanding of the technical aspects in the development of otic medicines. Plaintiffs bald conclusions are not enough to convince the Court otherwise. To the extent that he may testify about disputed facts, Professor Robinson's opinions are the proper subjects of cross-examination. See United States v.

Mitchell, 365 F.3d 215 (3d Cir. 2004); Walker v. Gordon, 46 Fed. Appx. 691 (3d Cir. 2002).

## II. CONCLUSION

For the foregoing reasons, Apotex's motions *in limine* to exclude the testimony of Richard Killworth and Phillip Beutel are **denied**. Furthermore, Daiichi's motion *in limine* to exclude or limit the testimony of Joseph Robinson is **denied**.

An appropriate Order follows.

/s/ William G. Bassler  
WILLIAM G. BASSLER, U.S.S.D.J.

Dated: November 1, 2005